DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 26, 2014

Plus Global
Mr. Peter Chung
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K140458
Trade/Device Name: Diotech Laser Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 15, 2014
Received: July 28, 2014

Dear Mr. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may; therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140458

Device Name
Diotech Laser Fibers

Indications for Use *(Describe)*
Diotech Laser Fibers (400µm, 600µm) is indicated for endovascular coagulation of the great saphenous vein in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the great saphenous vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremity. The Diotech Laser Fibers (400µm, 600µm) may be used with CW laser with wavelength range 810-1470nm, a power range 5-15W, using an SMA905 connector.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. Applicant Information

1) Company : Diotech Co.
2) Address : 301, Nakdong-daero, Saha-gu, Busan, Korea
3) Device : Diotech Laser Fibers
4) Phone Number : +82-51-292-6237
5) Fax Number : +82-51-292-6258
6) Homepage: http://www.diotech21.com

2. Device Information

1) Trade Name : Diotech Laser Fibers
2) Common Name : Diode Laser
3) Regulation Name : Laser surgical instrument for use in general and plastic surgery and in dermatology
4) Product code : GEX
5) Regulation number : 878.4810
6) Class of device : Class II

3. The legally marketed device to which we are claiming equivalence

1) 510(K) Number : K071959
2) Trade Name : AngioDynamics, Inc. NeverTouch 600 ㎛ Fiber
3) Product Code : GEX

4. Description of device

Diotech Laser Fiber is free- beam delivery device that transits laser energy into intended direction. Fiber length is 2.9mters. And catheter tube length is 0.85meters. Catheter tube marked on per 10㎜. This device can be connected with SMA905 connector and deliver to 810~1470㎛. This device can be connected with cleared surgical use laser diode.
This device is single use only and sterilized by EO gas.

5. Intended Use

Diotech Laser Fiber is indicated for endovascular cagulation of the great saphenous vein in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the great saphenous vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremity.
The Diotech Laser Fiber used with CW laser with wavelength range 810~1470nm, a power range 5~15W, using an SMA905 connector.

6. Technological Characteristics

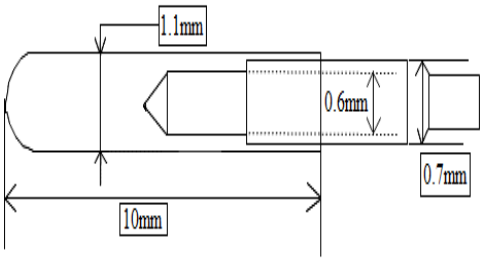
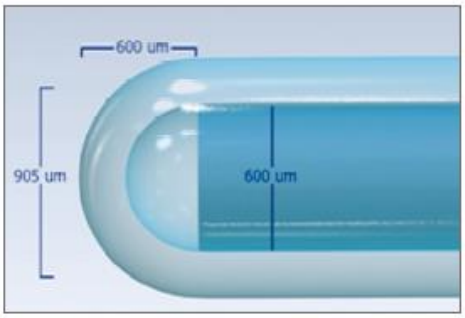
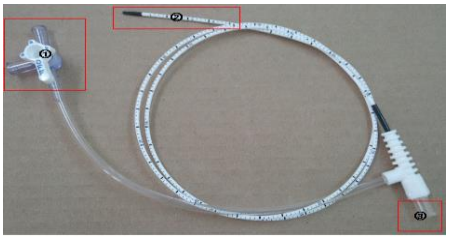
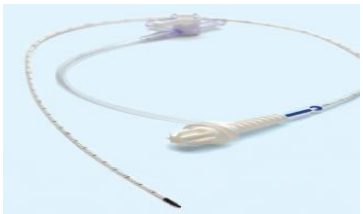
Diotech laser fiber consists of two parts that are optic fiber and catheter. The optic fiber also consists of connector, optical fiber, and the tip part. Fiber cable is made of the optical fiber that delivers the laser beam, and tip part is made of glass that can deliver the laser beam diagonally. And the fiber may be used any laser wavelength between 810~1470 ㎛ that have been cleared for surgical use diode laser. Outer diameter of fiber cable is 0.6mm and length is 2900 ㎜.
Catheter has a function that let the fiber cable be inserted into blood vessel as vein through its inner path. The catheter tube also consist of three parts as hub, tube and outer Inlet. Hub is used to connect with syringe. Tube is used for way that fiber cable may go through inner hole of tube. Outer Inlet is entrance hole for fiber to go through into tube. Catheter tube length is 0.85meters(850mm). It was marked on per 10mm to check depth to insert. The fiber core and cladding for the subject device are made from silica which is the same material used in the

predicate device. This device can be connected with SMA905 connector. This device is single use only and sterilized by EO gas.

7. Performance

Bench tests were performed. Bench testing included biocompatibility. The tests demonstrated that the device is as safe, as effective and performs in a substantially equivalent manner to the predicate device.

8. Predicate device comparison table

Trade Name			Diotech laser fiber	AngioDynamics, Inc. NeverTouch 600 ㎛ Fiber
Intended use			This device is indicated for endovascular coagulation of the great saphenous vein in patients with superficial vein reflux, for the treatment of varicose veins varicosities and associated with superficial reflux of the great saphenous vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremity.	The AngioDynamics, Inc. NeverTouch 600gm Fiber is indicated for endovascular coagulation of the great saphenous vein in patients with superficial vein reflux, for the treatment of varicose veins varicosities and associated with superficial reflux of the great saphenous vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremity.
510(k) Number			K140458	K071959
Fiber	Design			
	Diameter of Optical Fiber		0.6 ㎜(DRF-A600-1, DBF-A600-1) 0.4 ㎜(DBF-A400-1)	0.6 ㎜
	Diameter of Glass Tube		1.1 ㎜	0.905 ㎜
	Length of Glass Tube		10 ㎜	5.8 ㎜
Catheter	Design			
	Total Length		85 ㎝	80 ㎝ & 90 ㎝
	Operation Length		82 ㎝	83 ㎝
	Hub		5 ㎝	Similar
	Outer Inlet		1.5 ㎝	Similar
Material	Fiber	Optic Fiber	Silica	Silica
		Connector	Stainless steel	Stainless steel & Plastic
	Catheter	Hub	PP	Unknown
		Outer inlet	Polycarbonate	Unknown
		Tube	PE	PE
Fiber transmission angle			70~80°	30~50°
Wavelength range			810~1470nm	810~1470nm

Maximum output power	15W	Unknown
Single use	Single use	Single use
Biocompatibility	ISO10993	ISO10993
Sterility	EO gas sterilized	EO gas sterilized

9. Conclusion

The Device is investigated for function and effectiveness to compare the operation of function between Diotech laser fiber and predicate devices .

Comparison results demonstrate that the specifications and performance of the device are similar as functional and effective as the legally marketed predicate device.

Therefore, it is concluded that Diotech laser fiber is substantially equivalent to the legally marketed predicate device.